Welcome to the 12th Annual Patient-Reported Outcome Consortium Workshop

Event will begin at 11:01 am US ET

April 14-15, 2021

CRITICAL PATH INSTITUTE

collaborate · innovate · accelerate

Acknowledgments

- Critical Path Institute is supported by the U.S. Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) and is 55% funded by FDA/HHS, totaling $14,575,306, and 45% funded by non-government source(s), totaling $11,916,747. The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement by, FDA/HHS or the U.S. Government. For more information, please visit FDA.gov.
- Support for the ePRO Consortium comes from membership fees paid by members of the ePRO Consortium (https://c-path.org/programs/epro/).
- Additional support for the Patient-Reported Outcome (PRO) Consortium comes from membership fees paid by members of the PRO Consortium (https://c-path.org/programs/proc/).

Disclaimer

- The views and opinions expressed in the following slides are those of the individual presenters and should not be attributed to their respective organizations/companies, the U.S. Food and Drug Administration, or the Critical Path Institute.

- These slides are the intellectual property of the individual presenters and are protected under the copyright laws of the United States of America and other countries. All trademarks are the property of their respective owners.

eCOA: Getting Better Together Initiative Update

Sonya Eremenco, MA
Director, PRO Consortium
Acting Director, ePRO Consortium
Critical Path Institute

Agenda

- ePRO Consortium Overview
- Collaborations between Consortia
  - eCOA: Getting Better Together Initiative
  - COVID-19 Risk Assessment and Mitigation Strategies

Electronic Patient-Reported Outcome (ePRO) Consortium Overview

ePRO Consortium

- The ePRO Consortium was established by C-Path in 2011. Along with C-Path, the members of the ePRO Consortium are firms that provide electronic data collection technologies and services for capturing patient-reported outcome (PRO) and other clinical outcome assessment (COA) data in clinical trials.
- The mission of the ePRO Consortium is to advance the science of clinical trial endpoint assessment by collaboratively supporting and conducting research, designing and delivering educational opportunities, and developing and disseminating best practice recommendations for electronic collection of clinical outcome data.

ePRO Consortium: Members

ePRO Consortium Activities

The ePRO Consortium:

- Collaborates with PRO Consortium member firm representatives
- Interacts with regulatory agencies
- Provides scientific leadership for eCOA studies
- Performs electronic implementation assessments
- Provides educational opportunities
- Participates in innovative research
- Contributes to eCOA scientific literature
- Develops best practice recommendations

Collaborations between Consortia

eCOA: Getting Better Together Initiative

Background

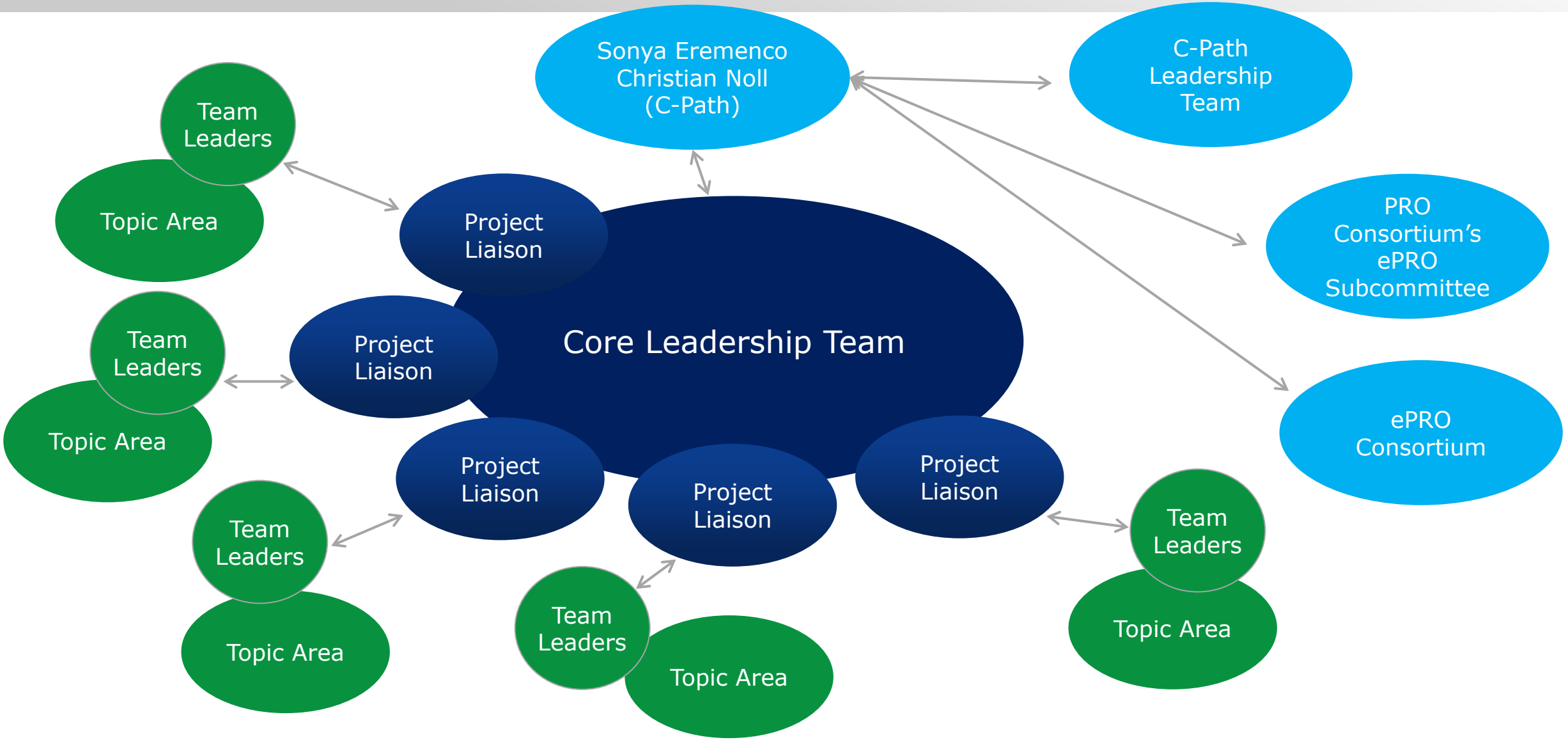
What it is:

A collaborative, pre-competitive initiative among C-Path, clinical trial sponsors from the PRO Consortium, eCOA providers from the ePRO Consortium, contract research organizations, and regulators (FDA)

Aims:

- Identify and address the root cause of issues with eCOA implementation in clinical trials
- Drive positive and lasting change in the eCOA ecosystem for the benefit of all stakeholders

Organizational Structure



Wave 1 Launch Date: June 2019
Topic 1: eCOA Lexicon

Project Liaison: Paul O'Donohoe (Medidata)
Project Team Leaders: Megan Turner (GSK) and Lisa Nguyen (MedAvante)

Objective:

- Without a common lexicon among eCOA vendors, sponsors, and regulators, the chance for miscommunication, errors, and inefficiencies increases. The objective of this team is to review the terminology and create an aligned eCOA Lexicon for use by stakeholders across the eCOA ecosystem.

Status:

- This project will likely run through the duration of Waves 1, 2, and 3.
- February 2021: Version 1 was completed and posted to the C-Path website.

Final Deliverable:

- A searchable PDF document is available via the webpages for the PRO Consortium (www.c-path.org/proc) and the ePRO Consortium (www.c-path.org/eproc).

Topic 2: eCOA Process/Workflow and Roles/Responsibilities

Project Liaison: Kate Zarzar (Genentech)
Project Team Leaders: Gena Gough (formerly of Clinical Ink) and Jennifer Lord-Bessen (BMS)

Objective:

- Define an aligned eCOA workflow or process aligning expectations for successful eCOA strategy development and deployment and clarifying roles and responsibilities.

Status:

- February 2021: Final documents were completed and posted to the C-Path website.

Final Deliverables:

- Searchable PDF documents are available via the webpages for the PRO Consortium (www.c-path.org/proc) and the ePRO Consortium (www.c-path.org/eproc).
  - Abbreviations, Roles, Process Step Table, Workflow

Topic 3: Best Practice Recommendations for User Acceptance Testing

Manuscript Title: *Best Practice Recommendations: User Acceptance Testing for Systems Designed to Collect Clinical Outcome Assessment Data Electronically*

Writing Team: The writing team includes members from the PRO Consortium's ePRO Subcommittee and the ePRO Consortium.

Status:

- The manuscript was approved by the Coordinating Committees of the ePRO Consortium and PRO Consortium.
- The writing team is preparing to submit the manuscript to *Therapeutic Innovation & Regulatory Science* for publication consideration.

Topic 4: Best Practice Recommendations for ePRO Dataset Structure and Standardization

Manuscript Title: *Best Practice Recommendations for ePRO Dataset Structure and Standardization to Support Drug Development*

Writing Team: The writing team includes stakeholders representing FDA, eCOA vendors, sponsors, CROs, analytic vendors, CDISC, the PRO Consortium's ePRO Subcommittee, and the ePRO Consortium.

Status:

- Progress on the manuscript is continuing
- First Draft Completed: Q2 2020
- Final Draft Target Date: Q3 2021
- Virtual Roundtable: Q4 2021

Topic 5: Best Practice Recommendations for Changing eCOA Data

Project Liaison: Trish Shepherd Delong (Janssen)
Project Team Leaders: Demian Humler (ERT) and Trish Shepherd Delong (Janssen)

Objective:

- Bring together experts across the eCOA ecosystem to develop best practices for handling COA data change requests.

Status:

- Develop manuscript outlining problems and best practices for:
  - Handling requests from investigators to change PRO and other COA data
  - Core principles and processes to address these requests
  - eClinical Forum representatives joined the project team in October 2020.

Final Deliverable:

- A manuscript published in a peer-reviewed publication with open access

Wave 2 Topics – 2020/2021

Wave 2 topics will begin on a rolling basis as projects in Wave 1 are completed.

- **Priority 1 – Q4 2020**
  Topic: Support flexible approaches to PRO data collection in terms of both timing and mode to reduce burden on study participants and sites while meeting regulatory requirements
  Objective: Develop best practice recommendations to support flexibility in PRO data collection
- **Priority 2 – Q4 2020**
  Topic: Bring Your Own Device (BYOD)
  Objective: Develop best practice recommendations for clinical trial implementation of BYOD
- **Priority 3 – Q3 2021**
  Topic: Data Management
  Objective: Develop best practice recommendations, with particular focus on the collaboration among sponsors, CROs, and eCOA partners
- **Priority 4 – Q4 2021**
  Topic: Site Readiness and Training
  Objective: Work with collaborators from the 2019 DIA Forum on eCOA training to leverage outputs and enhance published best practice recommendations

Wave 2 - Topic 1:
Support Flexible Approaches to PRO Data Collection

Project Liaison: Linda Nelsen (GSK)
Project Team Leaders: Linda Nelsen (GSK) and Valdo Arnera (ERT)

Topic: Support flexible approaches to PRO data collection in terms of both timing and mode to reduce burden on study participants and sites while meeting regulatory requirements

Objective: Develop best practice recommendations to support flexibility in PRO data collection

Timeframe: The goal is to finish this work in 12 months.

Status:

- The kick-off meeting for this project occurred on January 27, 2021.
- The project team has divided into 3 subgroups to focus on the following: 1) improving participant and site experience; 2) innovations in technology needed to support flexibility; and 3) instrument developer and regulatory perspectives.

Final Deliverable: TBD

Wave 2 - Topic 2:
Bring Your Own Device

Project Liaison: Shelly Steele (MedAvante)
Project Team Leaders: Karl McEvoy (Roche) and Lisa Charlton (Medrio)

Topic: Bring Your Own Device (BYOD)

Objective: Develop best practice recommendations for clinical trial implementation of BYOD

Timeframe: The goal is to finish this work in 12 months.

Status:

- The kick-off meeting for this project occurred on February 12, 2021.
- Phase 1 will focus on foundational aspects, defining BYOD and addressing measurement comparability and regulatory concerns.
- Phase 2 will address operational aspects and implementation of BYOD in clinical trials.

Final Deliverable:

- Webinar/Peer-reviewed manuscript

Wave 3 Topics – 2022/2023

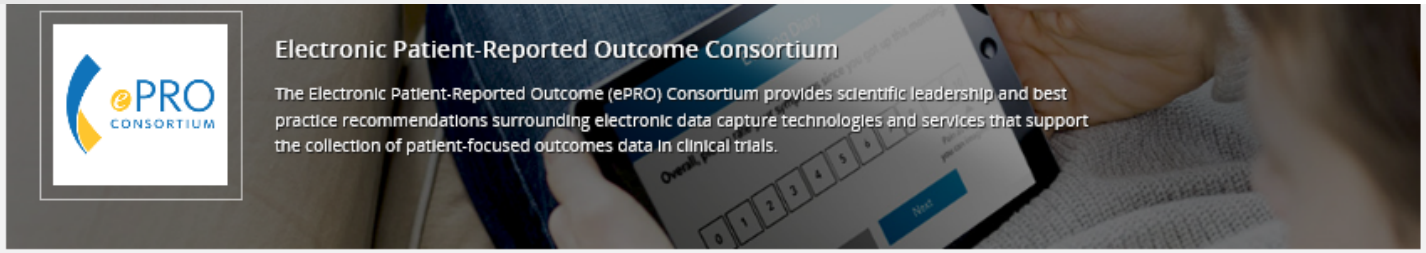
Wave 3 topics will begin on a rolling basis as projects in Wave 2 are completed.

- **Topic: Request for Proposal (RFP) – Order Form/Annotated Checklist and Best Practice Recommendations**
  Objective: Align expectations on and define the RFP process; outline best practices for sponsors, CROs, and eCOA providers
- **Topic: Design Requirements**
  Objective: Create best practice recommendations to define content when developing design requirements
- **Topic: Data Transfers**
  Objective: Develop an annotated data transfer agreement (DTA) template and best practice recommendations for operational aspects (e.g., timing and stakeholder responsibilities) of data transfers
- **Topic: eCOA Compliance Thresholds**
  Objective: Create best practice recommendations for the development, implementation, and evaluation of eCOA compliance thresholds to determine the impact of data collection thresholds on the clinical statistical analysis plan
- **Topic: Approaches to Optimizing Timelines and Efficiencies for eCOA Deployment**
  Objective: To be developed

eCOA: Getting Better Together Initiative - Available Resources

https://c-path.org/programs/eproc/

https://c-path.org/programs/proc/



Home > Programs > ePRO Consortium

OVERVIEW | Introduction | Best Practice Documents | Webinars | eCOA Initiative | Members | ePRO Consortium Team

eCOA: Getting Better Together Initiative

This initiative is a pre-competitive collaboration among Critical Path Institute, clinical trial sponsors from the Patient-Reported Outcome (PRO) Consortium, providers of electronic data collection technologies and services from the Electronic Patient-Reported Outcome (ePRO) Consortium, contract research organizations (CROs), and regulators (FDA). The initiative was launched in 2019 to identify and address the root cause of challenges with the implementation of clinical outcome assessments collected electronically (eCOA) in clinical trials, elevate eCOA improvement efforts to the clinical trial industry level, and drive positive and lasting change in the eCOA ecosystem.

Please click here to view the most recent quarterly update, which includes the status of current and future areas of focus.

eCOA: Getting Better Together Initiative

Resources

Name	Description	Links
eCOA Lexicon	Without a common lexicon among eCOA vendors, sponsors, and regulators, the chance for miscommunication, errors, and inefficiencies increases. The objective of this team is to review the terminology and create an aligned eCOA Lexicon for use by stakeholders across the eCOA ecosystem.	eCOA Lexicon
eCOA: Process/Workflow and Roles/Responsibilities	Define an eCOA process and workflow that aligns expectations for successful eCOA strategy development and deployment and clarifies roles and responsibilities.	Abbreviations Table Roles Table Process Step Table Process Workflow

UPCOMING EVENTS

Feb 17, 2021

CRITICAL PATH INSTITUTE

WEBINAR: eCOA: Getting Better Together Initiative – An Update from C-Path's PRO Consortium and ePRO Consortium

PAST EVENTS

Oct 29, 2020

ePRO CONSORTIUM

COVID-19: Risk Assessment and Mitigation Strategies for the Collection of PRO Data through Clinical Sites – Lessons Learned

More Events >>

PRESENTATIONS

Jun 25, 2019

Best Practices for the Electronic Migration and Implementation of Clinician-Reported Outcome Assessments in Clinical Trials

May 22, 2019

Measurement Comparability of Electronic and Paper Administered Visual Analogue Scales: A Review of Published Studies

Nov 10, 2018

Comparability of a Provisioned Device Versus Bring Your Own Device for Completion of Patient-Reported Outcome (PRO) Measures by Participants with Chronic Obstructive Pulmonary Disease (COPD): Quantitative Interview Findings

Coronavirus Disease 2019 (COVID-19): Risk Assessment and Mitigation Strategies for the Collection of Patient-Reported Outcome Data through Clinical Sites

Overview

- Members of the ePRO Consortium and the PRO Consortium were invited to collaborate on a risk assessment and mitigation plan for clinical trials in response to the impact of COVID-19.
- Over a 4-week period beginning in March 2020, member representatives participated in a series of teleconferences in which they engaged with others to provide suggestions for the assessment of risk and mitigation strategies for their firms.
- The resulting presentation focuses on the current challenges of capturing PRO data originally intended to be collected electronically (i.e., ePRO) from study participants during in-person visits to clinical trial sites.
- Recommended risk assessment and mitigation strategies are provided for consideration by trial sponsors and electronic clinical outcome assessment (eCOA) providers to facilitate the collection of PRO data in clinical trials.

Overview - Continued

- The presentation is available via C-Path's main website under News. The presentation is also posted in the Best Practice Documents section of the ePRO Consortium website.
- A webinar was presented on October 29, 2020, and a recording is available via the ePRO Consortium website under the Webinars section.

Contact Details

For further information about the ePRO Consortium and the eCOA: Getting Better Together Initiative, please contact us:

- Sonya Eremenco seremenco@c-path.org
- Christian Noll cnoll@c-path.org